SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6421–6440

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia), and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6421. Complex Z.A. (F.D.C. No. 44848. S. No. 32–875 R.)

QUANTITY: 29 ctns., 10 ampuls each, at New York, N.Y.

SHIPPED: During April 1960, from London, England, by Multipax Chemicals, Ltd.

LABEL IN PART: (Ctn.) "10 x 2.2 ml. Ampoules Complex Z.A. Each ampoule contains 2.2 ml. sterile aqueous solution of Zinc-Magnesium-Ascorbic Acid complexes equivalent to: Zinc Oxid. B.P. 1.85 mg. Mag. Chlorid. B.P.C. 3.00 mg. Acid. Ascorbic B.P. 30.00 mg. in 1 ml. Batch No. 108 * * * Edenhall Pharmaceutical Laboratories, Ltd. Sole Distributors: Multipax Chemicals Limited 142–146, Larkhall Lane, London, S.W. 4."

ACCOMPANYING LABELING: Leaflet in each carton entitled "To The Medical Profession Only * * * a new form of treatment in inoperable Neoplasm" and booklets entitled "To the Medical Profession Only Introducing 'Complex Z.A.' as a New Treatment for Inoperable Malignancy . . ."

LIBELED: 8–18–60, S. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for inoperable neoplasm, advanced malignancy, leukemia, Hodgkin's disease, and inoperable cancer; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: 9–16–60. Default—destruction.

6422. Phyltone capsules. (F.D.C. No. 42811. S. Nos. 24–177/9 P.)

QUANTITY: 57 100-capsule btls. and 33 30-capsule btls. at Phoenix, Ariz.

SHIPPED: Between 11–29–58 and 1–21–59, from Boling, Tex., by Texophyl Corp.

LABEL IN PART: (Btl.) "Phyltone Capsules Each Capsule Contains: ¼ Gram or 3¾ Grains Potassium Hydrogen Phytochlorin. Indicated for the treatment of Arteriosclerosis Arthritis and conditions of similar etiology. Manufactured by Texophyl Products, Boling, Texas. Dosage One capsule daily" and "Phyltone * * * ½ Gram Plant Porphyrins Dosage One Per Day Texophyl Corp. Boling, Texas."

ACCOMPANYING LABELING: Brochure entitled "Phyltone A Porphyrin Compound."

LIBELED: 2–9–59, Dist. Ariz.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for (on bottle label) arteriosclerosis, arthritis, and conditions of similar etiology, and (in brochure) resistant anemia, muscular atrophy, osteoporosis, impaired cerebration, depressive states, exhaustion, fatigue and manifest anoxia; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 2–1–61. Texophyl Corp., claimant, having answered the interrogatories filed by the Government and failing to pursue the matter further, and being in default, judgment of condemnation was entered and the article was ordered destroyed.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6423. Amphetamine tablets or capsules. (F.D.C. No. 44358. S. Nos. 70–946 P, 70–948 P, 70–952 P.)

QUANTITY: 15,000 *amphetamine tablets*, and an unknown quantity of *amphetamine tablets or capsules*, in possession of Chester Menk, t/a Shifting Sands Truck Stop, and Elmer Menk, in the vicinity of Oaktown, Ind.

SHIPPED: Prior to 3–2–60, from outside the State of Indiana.

LIBELED: On or about 3–2–60, S. Dist. Ind.

CHARGE: 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)(1)—the label of the article failed to bear the common or usual name of the drug; 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and the article was not exempt from such requirement since the article was in the possession of persons who were not regularly and law-